K113857

Synergetics™

APR 2 3 2012

510 (k) Summary of Safety and Effectiveness
Synergetics Single Use Directional Endo Ocular Laser Probe
Submitted in accordance with the requirements of 21 CFR 807.92

Applicant's Name and Address:	Synergetics, Inc. 3845 Corporate Centre Drive O'Fallon, MO 63368
Contact Person:	Gary Oliveros Synergetics, Inc. Senior Regulatory Affairs Specialist Telephone Number: (636) 794-5107 Fax Number: (636) 794-5120 Email: goliveros@synergeticsusa.com
Date Prepared:	December 29, 2011
Device Trade Name:	Synergetics™ Disposable Directional Endo Ocular Laser Probe
Common Name:	Sterile Single Use Endo Ocular Laser Probe
Device Classification:	21 CFR Part 886.4690, Ophthalmic Photocoagulater are Class II devices
Classification Name:	Photocoagulator and Accessories
Product Code:	HQB
FDA Panel:	Ophthalmic
Predicate Device:	Gamp and Associates Disposable Endoocular Laser Probe, K954307

Device Description:

The Synergetics™ Disposable Directional Endo Ocular Laser Probe is a sterile single use ophthalmic laser delivery device. The Laser Probe assembly includes a probe tip (distal end), a handpiece and a coupling means (proximal end) for connecting the Laser Probe to a commercially available laser source. Glass optic fiber protected by PVC tubing is provided between the handpiece and the coupling means. The probe tip, handpiece, tubing and coupling include a passageway for an optic fiber to transmit laser energy from the proximal end through the assembly to the distal end of the probe. The probe tip includes a rounded circumferential edge and smooth distal end surface to minimize tearing or snagging of tissue during insertion of the probe assembly through an incision at the sclera at pars plana.

The laser fibers work on the principle of total reflection. Laser energy is focused into the glass silica fiber at the proximal end of the probe and traverses the length of the fiber by means of total reflection. The fiber is

Synergetics™

able to contain the laser beam and funnels the laser energy from the laser through the proximal end through the assembly to the distal end of the laser probe.

Intended Use:

The Synergetics Disposable Directional Endo Ocular Laser Probe provides a mean for delivering endophotocoagulation during vitrectomy surgery.

Comparison of Technical Characteristics:

Criteria	Predicate Device – Gamp and Associates Disposable Endo Ocular Laser Probe - K954307	Synergetics Disposable Directional Endo Ocular Laser Probe
Intended Use	Provides a mean for delivering endophotocoagulation during vitrectomy surgery.	Provides a mean for delivering endophotocoagulation during vitrectomy surgery.
For Use With	HGM Laser, 905 SMA Connection	Lasers with 905 SMA Connection
Handle	Delrin	ABS with an ergonomic roller
Optical Fiber	Glass Optical Fiber – Silica Core	Glass Optical Fiber – Silica Core
Distal End	304 Stainless Steel Shaft	304 Stainless Steel Shaft with Nickel Titanium
Jacket	PVC	PVC
Coupling	SMA 905	SMA 905
Single Use	Yes	Yes
Sterilization Method	Ethylene Oxide (EtO)	Ethylene Oxide (EtO)
Packaging	Double Tyvek Pouch	Double Tyvek Pouch
Note 1: Synergetics packaging configuration has been validated in accordance with ISO 11607-1:2006, Packaging for Terminally Sterilized Medical Devices- Part 1: Requirements for Materials, Sterile Barrier Systems and Packaging Systems		

Risk Management:

Risk Management has been implemented and complies with ISO 14971, Medical Devices – Application of Risk Management to Medical Devices.

Sterilization Method:

Synergetics Disposable Directional Endo Ocular Laser Probes are sterilized in accordance with AAMI/ISO 11135 Medical Devices — Validation and routine control of ethylene oxide sterilization (EtO), Overkill Method for a sterility assurance level of 10^{-6}.

Summary of Non-clinical Testing:

Bench testing, and comparative performance testing to the predicate device, was performed on the Synergetics Disposable Directional Endo Ocular Laser Probe. The non-clinical testing indicates the device performance is substantially equivalent to the predicate and the slight differences raise no new issues of safety and effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

APR 2 3 2012

Synergetics USA, Inc.
% Mr. Gary Oliveros
Senior Regulatory Affairs Specialist
3845 Corporate Center Drive
O'Fallon, MO 63368

Re: K113857
Trade/Device Name: Synergetics Disposable Directional Endocular Laser Probe
Regulation Number: 21 CFR 886.4690
Regulation Name: Ophthalmic photocoagulator
Regulatory Class: Class II
Product Code: HQB
Dated: March 12, 2012
Received: March 13, 2012

Dear Mr. Oliveros:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Kesia Alexander

for

Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic, Neurological,
and Ear, Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Synergetics™

Synergetics™ 510 (k) Submission
Synergetics Single Use Directional Endo Ocular Laser Probe
Section 4 - Indications for Use

510(k) Number (if known):

Device Name: Synergetics Directional Endo Ocular Laser Probe

Indications for Use: The Synergetics Directional Endo Ocular Laser Probe provides a mean for delivering endophotocoagulation during vitrectomy surgery.

Prescription Use ___X___ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

510(k) Number K113857
